

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David Hung et al.

Atty. Docket: 005284.00198

Serial No.: To Be Assigned
(Division of Serial No.: 09/313,463)

Examiner: Unknown
Group Art Unit: Unknown

Filed: June 30, 2003

For: Methods For Identifying Treating Or Monitoring Asymptomatic Patients
For Risk Reduction Or Therapeutic Treatment Of Breast Cancer

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

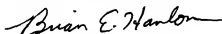
Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. § 1.56(a) Applicants submit herewith the references cited on the attached PTO-1449 forms.

Copies of these references are not submitted herewith, but can be found in parent application file U.S. Serial No. 09/313,463.

Applicants respectfully request that the Examiner consider these references in connection with the search of the prior art required by 37 C.F.R. § 1.104.

It is believed that no fee is required to ensure consideration of the cited references by the Examiner. However, if a fee is deemed necessary, the Commissioner is authorized to charge our Deposit Account No. 19-0733.

Respectfully submitted,



Brian E. Hanlon
Reg. No. 40,449

Date: 6/30/03
Banner & Witcoff, Ltd.
Eleventh Floor
1001 G Street, N.W.
Washington, D. C. 20001-4597
(202) 824-3000

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	To Be Assigned
Filing Date	June 30, 2003
First Named Inventor	David Hung
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	005284.00198

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Application Number	To Be Assigned
Filing Date	June 30, 2000
First Named Inventor	David Hung
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	005284.00198

Sheet

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of

Attorney Docket Number

005284.00198

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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FORM PTO-1449 (Modified)			Attorney Docket No.: 005284.00198		Application No.: TRA	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Applicant: David Hung			
			Filing Date: June 30, 2003		Group: Unknown	
Reference Designation			U.S. PATENT DOCUMENTS			
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
AA	3,608,540	09/28/71	Sartorius			
AB	3,786,801	01/22/74	Sartorius			
AC	5,478,556	12/26/95	Elliot, et al.			
AD	5,518,885	05/21/96	Raziuddin, et al.			
AE	5,527,528	06/18/96	Allen, et al.			
AF	5,798,266	08/25/98	Quay, et al.			
AG	5,914,238	06/22/99	Kessee, et al.			
AH	5,763,415	06/09/98	Sukamar			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
AI	WO 97/05898	02/20/97	PCT			
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
AJ	Arteaga et al, J Nat Cancer Inst. Jan. 6, 199; vol. 91 no. 1: 46-53					
AK	Barnes & Masood. "Potential value of hormone receptor assay in carcinoma in situ of breast" Am J. Cancer Prevention 11/90					
AL	Berntsen, et al. "Influence of Treatment with Aminoglutethimide on Plasma and Red-Blood-Cell Glutathione Status in Breast Cancer Patients." Cancer Chemother Pharmacol. 1998. Vol 42, pages 46-52.					
AM	Boccuzzi, et al. "Breast Duct Fluid Dehydroepiandrosterone sulphate in Fibrocystic Disease." European J. Cancer and Clinical Oncology. August 1987. Vol 23, pages 1099-1102					
AN	Buzdar, J Clin Oncol. 1998; Jan 16(1): 348-53					
AO	"Cancer detection techniques shown." Santa Barbara News Press 8/3/71					
AP	Cassels, "New test may speed breast cancer detection." The Medical Post March 20, 1973					
AQ	Ernster, et al. "Benign and malignant breast disease: initial study results of serum and breast fluid analyses of endogenous estrogens." J. Nat. Cancer Inst. vol 79 no. 5					
AR	Fabian, et al. "Biomarker and cytologic abnormalities in women at high and low risk for breast cancer" J. of Cellular Biochemistry 17G:153-160 (1993)					
AS	Fabian, et al. "Prevalence of abnormal biomarkers in fine needle breast aspirates in high risk populations." 1993 Proc. Ann Meeting Am Assoc. Cancer Res. 34: Abstract 1556					
AT	Fabian, "Who should receive which selective estrogen receptor modulator for prevention of breast cancer" The Breast Journal vol 5, no 3, 1999 211-214					
AU	"Finding asymptomatic breast cancer." Medical World News July 23, 1971					
AV	Fryckberg, et al. "Ductal carcinoma in situ of the breast. Surgery" Gynecology & Obstetrics 10/93 vol 177					
AW	Head, et al. "Assessment of immunologic competence and host reactivity against tumor antigens in breast cancer with vaccines." vol. 690 of the Annals of the NY Academy of Sciences 8/12/93					
AX	Imayama, et al. "Presence of elevated carcinoembryonic antigen on absorbent disks applied to nipple are of breast carcinoma patients." Cancer Sept 15, 1996 vol 78 no. 6					

FORM PTO-1449 (Modified)		Attorney Docket No.: 005284_00198	Application No.: TBA
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: DAVID HUNG et al.	
		Filing Date: June 30, 2003	Group: Unknown
AY	"Breast Fluid cells help in early cancer detection" JAMA May 7, 1973; vol 224, no. 6 pgs 823-827		
AZ	Osborne, New England J. Med. 1998; vol. 339, no.22: 1609-1618		
BA	King, et al. "Analytic studies of foam cells from breast cancer precursors." Cytometry 5:124-130 (1984)		
BB	King, et al. "Cellular composition of the nipple aspirate specimen of breast fluid." AJCP vol 64 Dec 1975 pp 728-738		
BC	Kristensen, et al. "A rare CYP19 (aromatase) variant may increase the risk of breast cancer." Pharmacogenetics. 1998. Vol. 8, pages 43-48		
BD	Lobsenz. "A new way to detect breast cancer early." Good House Keeping Jan 1975		
BE	Lu et al. "The Effects of Aromatase Inhibitors and Antiestrogens in the Nude Mouse Model." Breast Cancer Research and Treatment 1998. Vol 50, pages 63-71		
BF	Masood & Johnson. "The value of imprint cytology in cytochemical detection of steroid hormone receptors in breast cancer." AJCP vol 87 No 1 pp 30-36		
BG	Masood et al. Breast Health Challenges and Promises." J. Florida M.A. Aug/Sept 1996/Vol. 83, No. 7 pp459-465		
BH	Masood. "Fluorescent cytochemical detection of estrogen and progesterone receptors in breast fine-needle aspirates." AJCP Jan 1991		
BI	Masood. "The missing link: a 'pap smear' for early breast cancer detection and prevention." The Breast Journal, vol 5 number 1, 1999 pp. 1-2		
BJ	Nass, et al. "Breast cancer biology blossoms in the clinic." Nature Medicine vol 4 No. 7 July 1998		
BK	Norton, L Semin Oncol. 1997: Aug 24(4) Suppl 10; S10-3-S10-10		
BL	O'Regan et al, 1999 Am. Coll Surgeons vol. 188; no. 6 June 1999:678-684		
BM	Papanicolaou et al. "Exfoliative cytology of the human mammary gland and its value in the diagnosis of cancer and other diseases of the breast." Cancer March-April 1958, 11(2): 377-409		
BN	Pertschuk et al. "Estrogen receptor immunohistochemistry in endometrial carcinoma." Gynecologic oncology 63, 28-33 (1996) pp 28-33		
BO	Petrakis & King. "Genetic markers and cancer epidemiology." Cancer April supp 1977 vol 39 pp1861-1866		
BP	Petrakis et al. "Epithelial dysplasia in nipple aspirates of breast fluid: association with family history and other breast cancer risk factors." JNCI vol 68 no. 1 Jan 1982		
BQ	Petrakis, "Nipple aspirate fluid in epidemiologic studies of breast disease." Epidemiologic reviews vol 15 no. 1 1993		
BR	Rose et al. "A Comparison of Serum and Breast Duct Fluid Immunoassayable prolactin and Growth Hormon Woman and Patients with Cystic Breast Disease." Cancer, 01 December, 1987. Vol 60, No. 11, pages 2761-2765.		
BS	Sartorius et al. "The Biochemistry of breast cyst fluids and duct secretions." Breast Cancer Research and Treatment 35:255-266 1995		
BT	Sauter et al. "Prostate specific antigen levels in nipple aspirate fluid correlate with breast cancer risk" Cancer Epidemiology vol. 5, 967-970, Dec. 1996		
BU	Strah & Love. "The in situ carcinomas of the breast." JAMWA vol 47 No 5 Sept/Oct 1992		
BV	Sukumar & McKenzie, "Breast cancer prevention strategies for the twenty first century" Molecular Medicine Today Nov. 1996		
BW	Sukumar et al. "Independent molecular pathways in initiation and loss of hormone responsiveness of breast carcinomas." Science 22 April 1988		
BX	Tankanow, Am J Health Syst. Pharm 1998: Sept. 1 (55/17) pp. 1777-91		
BY	Wrensch, et al. "Breast cancer risk associated with abnormal cytology in nipple aspirates of breast fluid and prior history of breast biopsy." Am J. of Epidemiology vol 137 no. 8 1993		
BZ	Wynder et al. "Breast Secretion in Finnish Women: a metabolic epidemiologic study," Cancer 47: 1444-1450, 1981		
CA	Wynder et al. "Prolactin Oestrogen, and Lipids in Breast Fluid." The Lancet 22 October 1977. Vol. 2 No. 8043, pages 840-842.		

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of

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Application Number	TBA
Filing Date	June 30, 2003
First Named Inventor	David Hung
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	005284_00198

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		SNEIGE et al., "Fine-Needle Aspiration Cytology Of Ductal Hyperplasia With And Without Atypia And Ductal Carcinoma In Situ", Human Pathology, Vol. 25, No. 5, pp 465-492, May 5, 1996	
		KING et al., "Cellular Composition Of The Nipple Aspireate Specimen Of Breast Fluid I. The Benign Cells", American Journal Of Clinical Pathology, Vol. 64, No. 6, pp 728-745, 1975	
		PORTER-JORDAN and LIPPMAN, K., "Overview Of The Biological Markers Of Breast Cancer", Hematology – Oncology Clinics Of North America, Vol. 8, No. 1, pp 73-100, February 1994	
		BAE, H.W. et al., "Characterization Of The Promoter Region Of The Human Transforming Growth Factor-Beta Type II Receptor Gene", Journal of Biological Chemistry, Vol. 270, No. 49, pp. 29460-29468, December 8, 1995	
		MUNOZ-ANTONIA T. et al., "A Mutation In The Transforming Growth Factor Beta Type II Receptor Gene Promoter Associated With Loss Of Gene Expression", Cancer Research, Vol. 56, pp 4831-4835, November 1, 1996	
		Supplemental Partial European Search Report, EP 00 90 4589, March 25, 2003	

Examiner
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Considered

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		Filing Date: June 30, 2003		Group: Unknown	
Reference Designation		U.S. PATENT DOCUMENTS			
Examiner Initial	Document No.	Date	Name	Class	Filing Date (If Appropriate)
___ AA	4,202,329	05/13/80	Kortum		
___ AB	4,365,632	12/28/82	Kortum		
___ AC	4,981,692	01/01/91	Popescu et al.		
___ AD	5,763,415	06/09/98	Sukumar		
FOREIGN PATENT DOCUMENTS					
	Document No.	Date	Country	Class	Translation (Yes/No)
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)					
___ AE	Fisher et al., "Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant breast and bowel project P-1 study" Journal of the National Cancer Institute (1998) 90(18):1371-1388.				
___ AF	Goodson et al., "Discharges and secretions of the nipple" The Breast: Comprehensive Management of Benign & Malignant Diseases, Bland & Kirby, Eds., W.B. Saunders, Philadelphia, Second Edition, Chapter 4, (1998) 2:51-74.				
___ AG	King et al., "Nipple aspirate cytology for the study of breast cancer precursors" Journal of the National Cancer Institute (1983) 71:1115-1121.				
___ AH	Love et al., "Breast-duct endoscopy to study stages of cancerous breast disease" The Lancet (1996) 348:997-999.				
___ AI	Papanicolaou et al., "Exfoliative cytology of the human mammary gland and its value in the diagnosis of cancer and other diseases of the breast: Cancer (1958) 11(2):377-409.				
___ AJ	Sartorius et al., "Cytologic evaluation of breast fluid in the detection of breast disease" Journal of the National Cancer Institute (1977) 59(4):1073-1078.				
___ AK	Sauter et al., "Nipple aspirate fluid: A promising non-invasive method to identify cellular markers of breast cancer risk" British Journal of Cancer (1997) 76(4):494-501.				
___ AL	Wrensch et al., "Breast cancer incidence in women with abnormal cytology in nipple aspirates of breast fluid" American Journal of Epidemiology (1992) 135(2):130-141.				
EXAMINER		DATE CONSIDERED			

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		Filing Date: June 30, 2003	Group: Unknown
DB	Zippin & Petrakis, "Identification of high risk groups in breast cancer." Cancer vol 28 pp 1381-1387 Dec 1971		
DC	"Pap' test for breast cancer" a periodical clipping		
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